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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,575	04/03/2001	Ellen M. Beasley	CL000998	8695

25748 7590 05/11/2006

CELERA GENOMICS
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EXAMINER	
DANG, IAN D	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/824,575	BEASLEY ET AL.	
	Examiner	Art Unit	
	Ian Dang	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3 and 24-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 24-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II in the reply filed on March 8, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In the amendment filed on March 8, 2006, claims 1-2 and 4-23 have been cancelled and claims 24-36 have been added. The new claims 24-36 that have been added will be considered together with claim 3. Therefore, claims 3 and 24-36 are pending and under consideration in this examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 24-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Bull et al. et al. (WO 99/36533, published July 22, 1999, filed on January 18, 1999).

Claims 3 and 24 are drawn to an antibody or fragment thereof that selectively binds to a polypeptide consisting of SEQ ID NO:2. This language "selectively binds" as defined on page 34 includes cross-reactive antibodies.

This instant application claims an antibody to the polypeptide consisting of SEQ ID NO:2, which shares homology with several members of the ATPase aminophospholipid transporter family. Halleck et al. (1999) is cited as evidence that the polypeptide consisting of SEQ ID NO:2 (ATP8A2, class Σ-I b) has several conserved domains with FIC1 (ATP8B1, class Φ-I c) as disclosed on figure 2, page 142.

In claims 7 and 8 (page 57), Bull et al. disclose an antibody directed toward several stretches of amino acid residues (Bull's sequence in figure 3) of the FIC1 polypeptide (ATP8B1, class Φ-I c). These amino acid residues match Beasley's SEQ ID NO:2 as shown in alignment done at the USPTO (see enclosed alignment). For example, amino acid 885-898 residues of Bull et al. match to amino acid residues of 772-785 of the instant SEQ ID NO:2. The amino acid residues shared between the 2 sequences provide identical epitopes for the antibody disclosed by Bull et al. Thus Bull's antibody is able to cross-react and binds to the polypeptide consisting of SEQ ID NO:2 in this instant application.

The antibody disclosed by Bull et al. encompasses the limitations of claims 3 and 24.

Furthermore, the peptides of Bull's sequence as shown on figure 3 can be used to generate monoclonal antibodies (page 32) meeting the limitations of claims 25 and 26. In addition, these peptides can be used to obtain a fragment encoding a monoclonal antibody or a binding fragment (page 33, line 13-17) embracing the limitations of claims 35 and 36. Moreover, the antibody of Bull et al. can be labeled or detected by subsequent incubation with secondary labeled antibody encompassing the limitations of claims 28-30 (page 34, line 28-31). Finally, the antibody of Bull et al. can be in a formulation with suitable carriers and other agents to be incorporated into the formulation for administering the therapeutic agents (page 37, line 3-7) matching the limitations of claims 33-34.

Claims 3, and 24-36 are anticipated by Bull et al. (1999).

Citation of Art

The art made of record and not relied upon is considered pertinent to applicant's disclosure.

Liou et al. (WO 03/070758 A1 2003) disclose a SEQ ID NO:3 of WO 03/070758A1 coding for a human cation transport ATPase-like protein, which has over 99% identity with SEQ ID NO:2 of this instant application. In addition, Liou et al. teach a method of cation transport ATPase-like protein activity in Example 1 (page 50), expression of recombinant human cation transport ATPase-like protein Example 2 (page 50), and the identification of test compounds that modulate cation transport ATPase-like polypeptides Examples 3-5 (page 51-53).

In an abstract (abstract number 1208, published in October 1999, Hepatology, Vol.30, No.4 Part 2, pages 462A) at the annual meeting of the American Association for the Study of Liver Diseases, Ujhazy et al. disclosed a polyclonal antibody for detecting FIC1 (ATP8B1, class Φ-I c) protein in immunocytochemical studies. Subsequently, Ujhazy et al. (2001) published a complete study regarding the role for the familial intrahepatic cholestasis (fic 1) gene and protein in liver diseases. The polypeptide encoded by the fic 1 gene is share homologous stretches of amino acid residues with SEQ ID NO:2. Polyclonal antibodies against the FIC1 polypeptide were generated to study the function of this protein in this disease (column 2, page 769). Although the FIC1 polypeptide and the polypeptide consisting of SEQ ID NO:2 share common epitopes, the antibody of Ujhazy et al. does not bind to any of them.

Conclusion

No claims are allowed.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ian Dang
Patent Examiner
Art Unit 1647
May 9, 2006

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER

5/10/06

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